



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0495]

Agency Information Collection Activities; Proposed Collection; Comment Request;

Experimental Study on Consumer Responses to Nutrition Facts Labels With Various Footnote

Formats and Declaration of Amount of Added Sugars

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a study entitled “Experimental Study on Consumer Responses to Nutrition Facts Labels With Various Footnote Formats and Declaration of Amount of Added Sugars.”

DATES: Submit either electronic or written comments on the collection of information by

[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to

<http://www.regulations.gov>. Submit written comments on the collection of information to the

Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers

Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility;

(2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Experimental Study on Consumer Responses to Nutrition Facts Labels With Various Footnote  
Formats and Declaration of Amount of Added Sugars--(OMB Control Number 0910-New)

I. Background

Under the Nutrition Labeling and Education Act of 1990 (Public Law 101-535), the Nutrition Facts label is required on most packaged foods and this information must be provided in a specific format in accordance with the provisions of §101.9 (21 CFR 101.9). When FDA was determining which Nutrition Facts label format to require, the Agency undertook consumer research to evaluate alternatives (Refs. 1 to 3). More recently, FDA conducted qualitative consumer research on the format of the Nutrition Facts label on behalf of the Agency's Obesity Working Group (Ref. 4), which was formed in 2003 and tasked with outlining a plan to help confront the problem of obesity in the United States (Ref. 5). In addition to conducting consumer research, in the Federal Register of November 2, 2007 (72 FR 62149) FDA issued an Advance Notice of Proposed Rulemaking (ANPRM) entitled, "Food Labeling: Revision of Reference Values and Mandatory Nutrients" (the 2007 ANPRM), which requested comments on a variety of topics related to a future proposed rule to update the presentation of nutrients and content of nutrient values on food labels. In the 2007 ANPRM, the Agency included a request for comments on how consumers use the percent Daily Value in the Nutrition Facts label when evaluating the nutritional content of food items and making purchases.

Research has suggested that consumers use the Nutrition Facts label in various ways, including, but not limited to, using the Nutrition Facts label to determine if products are high or low in a specific nutrient and to compare products (Ref. 6). One component of the Nutrition Facts label that serves as an aid in these uses is the percent Daily Value. Early consumer research indicated that the percent Daily Value format improved consumers' abilities to make correct dietary judgments about a food in the context of a total daily diet (Ref. 3), which led FDA to require both quantitative and percentage declarations of nutrient Daily Values in the Nutrition Facts label in the 1993 Nutrition Labeling final rule (58 FR 2079, January 6, 1993).

Research in subsequent years, however, suggested that consumers' understanding and use of percent Daily Value may be somewhat inconsistent (Refs. 7 and 8). Additionally, FDA has received several public comments suggesting that further research on percent Daily Values may be warranted, along with research on other modifications to the Nutrition Facts label. Suggested research on potential modifications includes research on: (1) The removal of the statements, "Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs"; (2) the removal of the table in the footnote that lists the Daily Values for total fat, saturated fat, cholesterol, sodium, total carbohydrate, and dietary fiber based on 2,000 and 2,500 calorie diets as described in § 101.9(d)(9); and (3) changes to the presentation of and amount of information provided in the Nutrition Facts label. Therefore, the FDA, as part of its effort to promote public health, proposes to use this study to explore consumer responses to various food label formats for the footnote area of the Nutrition Facts label, including those that exhibit information such as various definitions for percent Daily Value, a succinct statement about daily caloric intake, and general guidelines for high and low nutrient levels.

This study will also explore how declaring the added sugars content of foods might affect consumers' attention to and understanding of the sugars and calorie contents and other information on the Nutrition Facts label. FDA received numerous comments regarding the declaration of added sugars in response to the 2007 ANPRM even though the Agency did not ask any questions regarding the declaration of added sugars. The Agency is not aware of any existing consumer research that has examined this topic and is therefore interested in using this study to enhance understanding of how consumers would comprehend and use this new information.

In the Federal Register of May 23, 2011 (76 FR 29758), FDA published a 60-day notice requesting public comment on the proposed collection of information. In that notice, the Agency announced its intention to examine consumer reactions to the declaration of vitamins and minerals by weight on the Nutrition Facts label. This intention was prompted by the 2003 Institute of Medicine report that recommended declaration of weight amounts of all nutrients, including vitamins and minerals, on the food label (Ref. 9). As the report noted, public health advice on nutrient intake is often given in absolute amounts, but in the case of a nutrient such as calcium, consumers may not be able to determine the amount of calcium in a food when it is listed only as Percent Daily Values on the Nutrition Facts label. Block and Peracchio (Ref. 10) demonstrated this difficulty and the potential merits of providing consumers with easy-to-use information in helping them increase their calcium intakes. The findings by Block and Peracchio provide data on the issue we were planning to study. On the other hand, consumer evidence on the effects of declaring added sugars is lacking. Therefore, the Agency has determined that the utility of the study would be enhanced by replacing the examination of declaring amounts of vitamins and minerals by weight with an examination of declaring the amount of added sugars.

This change would have minimal effects on the planned length and respondent burden of the study and would not change the study's primary focus, which remains on examining footnote options.

In the Federal Register of December 29, 2011 (76 FR 81949), FDA published a notice informing interested parties that the proposed collection of information had been submitted to OMB for review and clearance under the PRA and inviting the public to submit comments on the proposed study to OMB. The notice also announced FDA's plans to change the study by examining consumer reactions to the declaration of added sugars instead of the declaration of vitamins and minerals by weight. OMB received requests for an extension of time to comment on this change to the study. In response to these requests, FDA is providing an opportunity for comment on the current design of the study, including the added sugars component, by publishing a new 60-day notice describing the study as currently envisioned and inviting the public to submit comments to the Agency's docket. After considering any comments received, the Agency will resubmit the proposed collection of information to OMB. In the meantime, the Agency is withdrawing the proposed collection of information from OMB review, as announced elsewhere in this issue of the Federal Register.

The proposed collection of information is a controlled, randomized, experimental study. The study will use a Web-based survey, which will take about 15 minutes to complete, to collect information from 10,000 English-speaking adult members of an online consumer panel maintained by a contractor. The study will aim to recruit a sample that reflects the U.S. Census on gender, education, age, and ethnicity/race.

The study will randomly assign each of its participants to view a series of label images from a set of food labels that will be created for the study and systematically varied in the

presence or absence of: (1) A definition for percent Daily Value, (2) a general guideline for “high” and “low” nutrient levels, and (3) a declaration for added sugars. A sample definition for percent Daily Value may include, for example, “The percent Daily Value is the amount of a nutrient listed in this document that one serving of this product contributes to the daily diet.” A sample guideline for high and low nutrient levels may include, for example, “5 percent or less is low, and 20 percent or more is high.” Finally, the study will also examine effects of including reference to FDA within the Nutrition Facts footnote and a succinct statement about daily caloric intake. All label images will be mock-ups resembling food labels that may be found in the marketplace. Images will show product identity (e.g., yogurt or frozen meal), but not any real or fictitious brand name.

The survey will ask its participants to view label images and answer questions about their understanding, perceptions, and reactions related to the viewed label. The study will focus on the following types of consumer reactions: (1) Judgments about a food product in terms of its nutritional attributes and overall healthfulness; (2) ability to use the Nutrition Facts label in tasks, such as identifying a product’s nutrient contents and evaluating the percent Daily Values for specific nutrients; and (3) label perceptions (e.g., helpfulness and credibility). To help understand consumer reactions, the study will also collect information on participants' background, including but not limited to, use of the Nutrition Facts label and health status.

The study is part of the Agency's continuing effort to enable consumers to make informed dietary choices and construct healthful diets. Results of the study will be used primarily to enhance the Agency's understanding of how various potential modifications to the Nutrition Facts label may affect how consumers perceive a product or a label, which may in turn affect their dietary choices. Results of the study will not be used to develop population estimates.

To help design and refine the questionnaire, FDA plans to conduct cognitive interviews by screening 72 panelists in order to obtain 9 participants in the interviews. Each screening is expected to take 5 minutes (0.083 hour) and each cognitive interview is expected to take one hour. The total for cognitive interview activities is 15 hours (6 hours + 9 hours). Subsequently, we plan to conduct pretests of the questionnaire before it is administered in the study. We expect that 1,000 invitations, each taking 2 minutes (0.033 hours), will need to be sent to adult members of an online consumer panel to have 150 of them complete a 15-minute (0.25 hours) pretest. The total for the pretest activities is 71 hours (33 hours + 38 hours). For the survey, we estimate that 40,000 invitations, each taking 2 minutes (0.033 hours), will need to be sent to adult members of an online consumer panel to have 10,000 of them complete a 15-minute (0.25 hours) questionnaire. The total for the survey activities is 3,820 hours (1,320 hours + 2,500 hours). Thus, the total estimated burden is 3,906 hours.

FDA estimates the burden of this collection of information as follows:

| Activity                     | No. of Respondents | No. of Responses per Respondent | Total Annual Responses | Average Burden per Response | Total Hours |
|------------------------------|--------------------|---------------------------------|------------------------|-----------------------------|-------------|
| Cognitive interview screener | 72                 | 1                               | 72                     | 0.083<br>(5 min.)           | 6           |
| Cognitive interview          | 9                  | 1                               | 9                      | 1                           | 9           |
| Pretest invitation           | 1,000              | 1                               | 1,000                  | 0.033<br>(2 min.)           | 33          |
| Pretest                      | 150                | 1                               | 150                    | 0.25<br>(15 min.)           | 38          |
| Survey invitation            | 40,000             | 1                               | 40,000                 | 0.033<br>(2 min.)           | 1,320       |
| Survey                       | 10,000             | 1                               | 10,000                 | 0.25<br>(15 min.)           | 2,500       |
| Total                        |                    |                                 |                        |                             | 3,906       |

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

## II. References



The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

1. Levy, A.S., S.B. Fein, and R.E. Schucker, "Nutrition Labeling Formats: Performance and Preference," Food Technology, vol. 45, pp. 116-121, 1991.

2. Levy, A.S., S.B. Fein, and R.E. Schucker, "More Effective Nutrition Label Formats Are Not Necessarily Preferred," Journal of the American Dietetic Association, vol. 92, pp. 1230-1234, 1992.

3. Levy, A.S., S.B. Fein, and R.E. Schucker, "Performance Characteristics of Seven Nutrition Label Formats," Journal of Public Policy and Marketing, vol. 15, pp. 1-15, 1996.

4. Lando, A.M. and J. Labiner-Wolfe, "Helping Consumers to Make More Healthful Food Choices: Consumer Views on Modifying Food Labels and Providing Point-of-Purchase Nutrition Information at Quick-Service Restaurants," Journal of Nutrition Education and Behavior, vol. 39, pp. 157-163, 2007.

5. U.S. Food and Drug Administration, Calories Count: Report of the Working Group on Obesity, 2004, available at <http://www.fda.gov/Food/LabelingNutrition/ReportsResearch/ucm081696.htm>.

6. U.S. Food and Drug Administration, "2008 Health and Diet Survey--Preliminary Topline Frequencies (Weighted)," 2010, available at <http://www.fda.gov/Food/ScienceResearch/ResearchAreas/ConsumerResearch/ucm193895.htm>.

7. Li, F., P.W. Miniard, and M.J. Barone, “The Facilitating Influence of Consumer Knowledge on the Effectiveness of Daily Value Reference Information,” Journal of the Academy of Marketing Science, vol. 28, pp. 425-436, 2000.

8. Levy, L., R.E. Patterson, A.R. Kristal, and S.S. Li, “How Well Do Consumers Understand Percentage Daily Value on Food Labels?” American Journal of Health Promotion, vol. 14, pp. 157-160, 2000.

9. Institute of Medicine. Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification, 2003, available at [http://www.nap.edu/catalog.php?record\\_id=10872](http://www.nap.edu/catalog.php?record_id=10872).

10. Block, L.G. and L.A. Peracchio, “The Calcium Quandary: How Consumers Use Nutrition Labels,” Journal of Public Policy and Marketing, vol. 25, pp. 188-196, 2006.

Dated: May 23, 2012.

Leslie Kux,

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